

Exhibit D

1 IN THE UNITED STATES DISTRICT COURT
2 FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
3 CHARLESTON DIVISION

4 IN RE: ETHICON, INC., PELVIC :Master File No.
5 REPAIR SYSTEM PRODUCTS :2:12-MD-02327
6 LIABILITY LITIGATION :MDL No. 2327

7 -----
8 THIS DOCUMENT RELATES TO :JOSEPH R. GOODWIN
9 THE CASES LISTED BELOW :U.S. DISTRICT JUDGE
10 -----

| | | |
|----|-----------------------|---------------|
| 11 | Mullins, et al. v. | 2:12-cv-02952 |
| 12 | Ethicon, Inc., et al. | |
| 13 | Sprout, et al. v. | 2:12-cv-07924 |
| 14 | Ethicon, Inc., et al. | |
| 15 | Iquinto v. Ethicon, | 2:12-cv-09765 |
| 16 | Inc., et al. | |
| 17 | Daniel, et al. v. | 2:13-cv-02565 |
| 18 | Ethicon, Inc., et al. | |
| 19 | Dillon, et al. v. | 2:13-cv-02919 |
| 20 | Ethicon, Inc., et al. | |
| 21 | Webb, et al. v. | 2:13-cv-04517 |
| 22 | Ethicon, Inc., et al. | |
| 23 | Martinez v. Ethicon, | 2:13-cv-04730 |
| 24 | Inc., et al. | |
| 25 | McIntyre, et al. v. | 2:13-cv-07283 |
| | Ethicon, Inc., et al. | |
| | Oxley v. Ethicon, | 2:13-cv-10150 |
| | Inc., et al. | |
| | Atkins, et al. v. | 2:13-cv-11022 |
| | Ethicon, Inc., et al. | |
| | Garcia v. Ethicon, | 2:13-cv-14355 |
| | Inc., et al. | |
| | Lowe v. Ethicon, | 2:13-cv-14718 |
| | Inc., et al. | |
| | Dameron, et al. v. | 2:13-cv-14799 |
| | Ethicon, Inc., et al. | |
| | Vanbuskir, et al. v. | 2:13-cv-16183 |
| | Ethicon, Inc., et al. | |

21
22 OCTOBER 5, 2015

23 MICHAEL P. WOODS, M.D.

24 GOLKOW TECHNOLOGIES, INC.

25 877.370.3377 ph|917.591.5672 fax

 deps@golkow.com

| | | |
|----|--------------------------|---------------|
| 1 | CAPTION CONTINUED: | |
| 2 | Mullens, et al. v. | 2:13-cv-16564 |
| | Ethicon, Inc., et al. | |
| 3 | Shears, et al. v. | 2:13-cv-17012 |
| | Ethicon, Inc., et al. | |
| 4 | Javins, et al. v. | 2:13-cv-18479 |
| | Ethicon, Inc., et al. | |
| 5 | Barr, et al. v. | 2:13-cv-22606 |
| | Ethicon, Inc., et al. | |
| 6 | Lambert v. Ethicon, | 2:13-cv-24393 |
| | Inc., et al. | |
| 7 | Cook v. Ethicon, Inc., | 2:13-cv-29260 |
| | et al. | |
| 8 | Stevens v. Ethicon, | 2:13-cv-29918 |
| | Inc., et al. | |
| 9 | Harmon v. Ethicon, Inc., | 2:13-cv-31818 |
| | et al. | |
| 10 | Snodgrass v. Ethicon, | 2:13-cv-31881 |
| | Inc., et al. | |
| 11 | Miller v. Ethicon, Inc., | 2:13-cv-32627 |
| | et al. | |
| 12 | Matney, et al. v. | 2:14-cv-09195 |
| | Ethicon, Inc., et al. | |
| 13 | Jones, et al. v. | 2:14-cv-09517 |
| | Ethicon, Inc., et al. | |
| 14 | Humbert v. Ethicon, | 2:14-cv-10640 |
| | Inc., et al. | |
| 15 | Gillum, et al. v. | 2:14-cv-12756 |
| | Ethicon, Inc., et al. | |
| 16 | Whisner, et al. v. | 2:14-cv-13023 |
| | Ethicon, Inc., et al. | |
| 17 | Tomblin v. Ethicon, | 2:14-cv-14664 |
| | Inc., et al. | |
| 18 | Schepleng v. Ethicon, | 2:14-cv-16061 |
| | Inc., et al. | |
| 19 | Tyler, et al. v. | 2:14-cv-19110 |
| | Ethicon, Inc., et al. | |
| 20 | Kelly, et al. v. | 2:14-cv-22079 |
| | Ethicon, Inc., et al. | |
| 21 | Lundell v. Ethicon, | 2:14-cv-24911 |
| | Inc., et al. | |
| 22 | Cheshire, et al. v. | 2:14-cv-24999 |
| | Ethicon, Inc., et al. | |
| 23 | Burgoyne, et al. v. | 2:14-cv-28620 |
| | Ethicon, Inc., et al. | |
| 24 | Bennett, et al. v. | 2:14-cv-29624 |
| | Ethicon, Inc., et al. | |
| 25 | | |

1 BY MR. KUNTZ:

2 Q. You can -- and you're going to say that
3 over and over again, I know that, and Burt can ask
4 you those questions, but just answer my question for
5 now. Okay?

6 A. I'm aware of the internal documents.

7 Q. Okay. So the answer -- your answer is,
8 yes, Ethicon knew of all of the risks that you listed
9 out for me prior to the launch of the TVT?

10 MR. SNELL: Objection: Misstates,
11 totally misstates. He said he's aware of the
12 documents, but he did not consider that. You're
13 misstating his testimony.

14 BY MR. KUNTZ:

15 Q. Okay. So you did not consider the Ethicon
16 internal documents when forming your opinions that
17 you're here to talk about today?

18 A. Absolutely not.

19 Q. Okay. So you don't rely on any Ethicon
20 internal design documents in forming or giving your
21 opinions today?

22 A. I am looking at the evidence-based data
23 that's available.

24 Q. I think you just said, "Absolutely not."
25 Did you rely on any Ethicon design internal documents

1 in forming and rendering your opinions that you're
2 talking about today?

3 A. No.

4 Q. How many -- when I talk about TVT
5 Retropubic, I'm talking about the Ethicon product.

6 A. Yes.

7 Q. Okay. Do you understand that?

8 A. Yes.

9 Q. Okay. How many TVT Retropubic devices have
10 you placed in your career?

11 A. Retropubic? A couple thousand.

12 Q. Okay. 2,000?

13 A. I would say plus or minus 500, yes.

14 Q. Okay. Do you keep track of that number?

15 A. I do not actively keep track of it anymore.

16 Q. Okay. When did you stop keeping track of
17 it?

18 A. I'm still using Retropubic TVT, but I would
19 say probably around 2007.

20 Q. Okay. So you kept track of how many TVT
21 Retropubic devices you used up until 2007, correct?

22 A. 2007 or 2008.

23 Q. Okay. Where is that list?

24 A. I don't have it here.

25 Q. Okay. But you do have it, right? We can

1 do you do with warnings with those three groups?

2 A. Actually, looking on the safety design for,
3 say, obstetrical units and these kind of things.

4 Q. Okay. What do you mean safety design? For
5 the actual unit at the hospital?

6 A. Yes.

7 Q. Okay. So you work with warnings for, like,
8 beds in hallways?

9 A. Well, what I do is looking at hospital
10 design or team design for patient safety, is a better
11 way to describe it.

12 Q. You're not an expert on warnings related to
13 medical devices, correct?

14 A. No, I would not call myself an expert.

15 Q. Okay. I mean, you don't know what risk
16 information a medical device company needs to put
17 inside an IFU, do you?

18 MR. SNELL: Objection, form.

19 THE WITNESS: I believe that the FDA
20 has very specific guidelines.

21 BY MR. KUNTZ:

22 Q. Okay. You don't know what those are as we
23 sit here today?

24 A. No, I do not.

25 Q. Okay. You've never looked at them, have

1 you?

2 A. Not the guidelines from the FDA, no.

3 Q. You've never drafted an IFU for a medical
4 device?

5 A. No.

6 Q. You've never worked on warnings for a
7 medical device?

8 A. Not that I recall, no.

9 Q. Okay. You have never worked on warnings
10 for a prescription drug?

11 A. No.

12 Q. You're not a biomedical engineer?

13 A. No, I am not.

14 Q. You would agree you're not an expert on the
15 design of medical devices?

16 MR. SNELL: Form.

17 THE WITNESS: I have worked on medical
18 devices that have been patented, as a consultant.

19 BY MR. KUNTZ:

20 Q. Have you ever designed a medical device?

21 A. Actually, I worked on the design of the
22 LigaSure Extend clamp for vaginal hysterectomy.

23 Q. Okay. Who manufactured that product?

24 A. Valleylab.

25 Q. What was your role in the design of that

1 medical device?

2 A. Looking at the length of the clamp and what
3 I felt would be effective for deep pelvises. Also,
4 they consulted me on the development of the LigaSure
5 Precise, which was a small clamp for ENT.

6 Q. Okay. Do you have a patent on medical
7 devices?

8 A. No, I do not.

9 Q. When was this -- when was this device
10 created?

11 A. The LigaSure Extend?

12 Q. Yes.

13 A. I don't know the exact date. It's been on
14 the market for quite a while. It had to be the early
15 2000s.

16 Q. Okay.

17 A. It might -- might have been even the late
18 1990s, but somewhere in that category. The Precise,
19 I'm not sure when it came out.

20 Q. What standards do manufacturers have to
21 follow in designing medical devices?

22 A. That it -- they state that what it does is
23 actually what it does, but beyond that, I don't have
24 a tremendous amount of knowledge.

25 Q. Do you know what government standards they

1 study, and it was either late 1990s or early 2000s.

2 Q. Okay. So you ran a study for them after
3 the product was designed?

4 A. No. I had done using another device that
5 was shorter on a vaginal hysterectomy randomized
6 study.

7 Q. Do you know what a company research is
8 before a product is designed or released?

9 MR. SNELL: Form, vague, overbroad,
10 incomplete hypothetical.

11 BY MR. KUNTZ:

12 Q. You can answer.

13 A. I have vague ideas, but I -- I have no
14 solid regulatory aspect at all.

15 Q. Okay.

16 A. I'm usually asked, you know, such as with
17 my work with Ethicon is, "What is your opinion on
18 this?" I worked on a couple of the other -- the
19 other, like with TVT Secur, and then looking at some
20 of the evolution ones, but as in the regulation, that
21 is something that's not what I would -- I've got
22 other things to be worried about.

23 Q. You wouldn't consider yourself an expert in
24 that area?

25 A. Pardon me?

1 Q. You're not an expert in that area, correct?

2 MR. SNELL: Form, "that area."

3 THE WITNESS: I feel that I do not
4 have the knowledge base. I may have a very vague
5 knowledge base but not the level that would be
6 required in manufacturing.

7 BY MR. KUNTZ:

8 Q. Tell me how a medical device company goes
9 about designing a medical device.

10 MR. SNELL: Objection: Form,
11 overbroad.

12 THE WITNESS: I feel that in the
13 device they get an idea, and they do benchtop work,
14 and then it evolves through; and I would say I'm more
15 at the end of that process.

16 BY MR. KUNTZ:

17 Q. Okay. What experts are involved?

18 A. It would depend on what type of device.

19 Q. What about an SUI device?

20 A. I believe that with that you would have to
21 have your mechanical engineers, you would have to
22 have your safety individuals, you would have to have
23 consulting with medical personnel, "Is this even a
24 real option to be looking at?"

25 Q. What's a design history file?

1 A. I -- again, I -- I would suspect, by that
2 name, that it is the life -- the evolution of a
3 device.

4 Q. Okay. Did you review the design history
5 file for the TVT Retropubic?

6 A. I reviewed over -- I don't recall
7 specifically on that. When Ulmsten was first coming
8 out with this, with the integral theory, I found it
9 to be a real challenge to my dogma, for one, but in
10 looking at how he talked about using the various
11 suburethral components, I did look at that.

12 Q. Okay. Do you know, one way or another, if
13 you reviewed the design history file for the TVT, as
14 we sit here right now?

15 A. I did not. I do not have a bundle that
16 says that's what it is, no.

17 Q. Okay. Do you know what MedScan is?

18 A. I've heard of it. I'm not exactly -- I
19 believe that is -- I will say it would be pure
20 conjecture on --

21 Q. Do you know what Preventia is? Have you
22 ever heard of Preventia?

23 A. No. Actually, I might have heard -- the
24 name sounds, but...

25 Q. What's a failure modes and effects

1 analysis?

2 A. I'm not sure.

3 Q. So safe to -- it's accurate to say you're
4 not sure what the purpose of a failure modes and
5 effects analysis is because you don't know what it
6 is?

7 A. Correct.

8 Q. Do you know -- do you recall, as you sit
9 here now, if you reviewed any of the failure modes
10 and effects analysis involved in this case?

11 A. If I did, it would have been very briefly.

12 Q. Do you know if warnings for a product are
13 part of the failure modes analysis?

14 A. If I don't know exactly what the failure
15 modes analysis is, I can't say that.

16 Q. Do you know what a DDSA is?

17 A. That name rings a bell. I'm trying --

18 Q. So you don't know, as we sit here right
19 now, or you don't recall?

20 A. Don't -- do not recall.

21 Q. What is ISO testing?

22 A. ISO testing is a standardized testing that
23 is used -- it's International Standards -- I want to
24 say Organization. I remember this some from my ICON
25 days.

1 something that I'm just starting to do. Also,
2 assessing is the quality of life or when I see them
3 for their immediate post-op check, which is usually
4 at about four weeks, I'm assessing: Is the tissue
5 healed, is it tender, are they happy with the
6 results, making sure that they're not in retention,
7 and I always ask them, "Is your life better?"

8 Q. Okay. And what -- from a patient
9 satisfaction standpoint, what is the success rate for
10 TVT?

11 A. In my own hands, it's probably about 95,
12 96 percent.

13 Q. What about in the literature?

14 A. The literature is variable but in the upper
15 80s to low 90s.

16 Q. Have you seen studies that put it below?

17 A. Yes, there are studies out there, but when
18 you look at the randomized controlled studies or the
19 meta-analysis or such Cochrane reviews or such as the
20 SGS, they're in the 80 range.

21 Q. Do you use any synthetic mesh for prolapse
22 repair?

23 A. I do for sacrocolpopexy, and recently I did
24 have a patient that I used a vaginal approach, that I
25 cut because there was a very large defect on one side

1 Q. So this is a mental list?

2 A. Yes.

3 Q. So you don't have any list anywhere where
4 you have exact numbers written down on a spreadsheet
5 or piece of paper --

6 A. No.

7 Q. -- for the amount you've implanted?

8 A. No.

9 Q. Okay. For the amount you've done
10 reoperations on?

11 A. No.

12 Q. Okay.

13 A. I mean, there would probably be some
14 billing records, or something, somewhere where we
15 could look, but...

16 Q. So you could maybe find that number if you
17 looked for it?

18 A. Actually, I'm no longer using that billing
19 service and so I'm not sure I could find it using the
20 billing.

21 Q. And does that go for your erosion rate,
22 too; that's a guesstimate, that's not something you
23 keep hard numbers on?

24 A. No, I don't keep hard numbers on.

25 Q. Okay. So you don't keep hard numbers on

1 the type of operations you do, correct?

2 MR. SNELL: Objection, misstates.

3 THE WITNESS: Correct.

4 MR. SNELL: Did you say types?

5 MR. KUNTZ: Yeah.

6 MR. SNELL: That's a misstatement.

7 Object, form.

8 BY MR. KUNTZ:

9 Q. Do you keep numbers anywhere besides your
10 head of any operations you do?

11 A. Yes.

12 Q. Where?

13 A. They would be in billing records and
14 things, but I don't have those available to me.

15 Q. Can you get those?

16 A. I do not know if I can get those.

17 Q. Okay. And when you looked and you put
18 numbers in your expert report of 1 percent erosion
19 rate, 2 to 3 reoperation rate, that's all coming from
20 your head, correct?

21 A. My data closely reflects the data that's
22 out there, yes.

23 Q. That wasn't my question. All of those
24 numbers in your report came from your mental
25 estimates as opposed to looking at any hard data or

1 numbers to make those determinations; is that
2 accurate?

3 A. I would say that that is reasonably
4 accurate.

5 Q. Have you ever removed or revised mesh
6 because of pain?

7 A. I talked about the one earlier where this
8 was a urologist that sent a patient in that had an
9 ilioinguinal nerve pain that responded to a block.
10 And then I excised that part above the fascia.

11 Q. Do you believe TVT Exact is the gold
12 standard?

13 A. I do not believe that the randomized
14 control studies are going to suggest a gold standard
15 for anything but Retropubic, whether it's TVT or TVT
16 Exact.

17 Q. Okay. Do you think the mechanical cut mesh
18 is the gold standard or the laser cut mesh?

19 A. I believe that the data shows in the long
20 term that mechanical cut was the gold standard. But
21 the change, and as we've talked about earlier, is do
22 the studies delineate whether it's laser cut or
23 mechanically cut, and that I -- that I cannot expound
24 upon.

25 Q. Is the AMS MiniArc the gold standard?

1 MR. KUNTZ: Objection.

2 THE WITNESS: I kept a running mental
3 log.

4 BY MR. SNELL:

5 Q. Just like you would have kept a running
6 mental log of how many Burches or autologous slings
7 you did --

8 A. Yes.

9 Q. -- before that?

10 A. Yes.

11 Q. The fact that you didn't write down the
12 exact number you did in a certain month or year, does
13 that make your estimate unreliable with regard to the
14 number of TVT Retropubic devices that you have used
15 in your career?

16 MR. KUNTZ: Objection.

17 THE WITNESS: No. I think that it's a
18 ballpark figure that is probably fairly close.

19 BY MR. SNELL:

20 Q. Such that there is no doubt in your mind
21 whatsoever that you -- do you believe you have
22 extensively used the TVT Retropubic device to treat
23 stress incontinence in women?

24 A. Yes.

25 Q. For your complication rates, did you follow